Rīgas Stradiņa universitāte

Bioētikas aktuālie jautājumi pētniecībā

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2021. gada 1. decembris,

RSU Zinātnieku brokastis

Ētikas atļaujas un datu pārvaldība pētījumos: Kad, ko un kā darīt

Labāka zinātne: *research integrity*

Area	Topic	Action
Support	Research environment	Ensure fair assessment procedures and prevent hypercompetition and excessive publication pressure.
Support	Supervision and mentoring	Create clear guidelines for PhD supervision (such as on meeting frequency); set up skills training and mentoring.
Support	Integrity training	Establish training and confidential counselling for all researchers.
Organization	Ethics structures	Establish review procedures that accommodate different types of research and disciplines.
Organization	Integrity breaches	Formalize procedures that protect both whistle-blowers and those accused of misconduct.
Organization	Data practices and management	Provide training, incentives and infrastructure to curate and share data according to FAIR principles.
Communication	Research collaboration	Establish sound rules for transparent working with industry and international partners.
Communication	Declaration of interests	State conflicts (financial and personal) in research, review and other professional activities.
Communication	Publication and communication	Respect guidelines for authorship and ensure openness and clarity in public engagement.

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FAIR data are data which meet principles of findability, accessibility, interoperability, and reusability

Research integrity: nine ways to move from talk to walk
https://www.nature.com/articles/d41586-020-02847-8

EU Grants

How to complete your ethics self-assessment

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https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

1 HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		YES/NO		Information to be provided in the proposal	Documents be provided/kept on file
Does your activity involve Human Embryonic Stem Cells (hESCs)?		☐	☐		
If **YES:**	Will they be directly derived from embryos within this project?	☐	☐	*Activity not eligible for funding*	*Activity not eligible for funding*
	Are they previously established cells lines? Are the cell lines registered in the European registry for human embryonic stem cell lines?	☐	☐	1) Origin and line of cells. 2) Details on licensing and control measures by the competent authorities of the Member States involved 3) Declaration confirming that the 6 specific conditions *(see below)* for activities involving human embryonic stem cells are met.	1) Copies of ethics approval. 2) Declaration that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hpscreg.eu).
Does your activity involve the use of human embryos?		☐	☐	1) Origin of embryos. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Confirmation that informed consent has been obtained.	1) Copies of ethics approval. 2) Informed consent forms and information sheets.
If **YES:**	Will the activity lead to their destruction?	☐	☐	*Activity not eligible for funding*	*Activity not eligible for funding*
Does your activity involve the use of other human embryonic or foetal tissues / cells?		☐	☐	*See section 3 below*	

2 HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
Does your activity involve human participants?		☐	☐	Please provide information in one of the subcategories below	
If **YES:**	Are they volunteers?	☐	☐	1) Details on recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on unexpected findings policy.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are they healthy volunteers for medical studies?	☐	☐	1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on incidental findings policy.	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.
	Are they patients for	☐	☐	1) Details on the	1) Copies of ethics
Does your activity involve conducting a clinical study as defined by the Clinical Trial Regulation 536/2014 (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)? *(n/a for DEP)*		☐	☐		
If **YES:**	Is it a clinical trial?	☐	☐	1) Details on the medical products that are being used and risk assessment. 2) Details on the disease/condition /disability of the participants 3) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 4) Details on the incidental findings policy	1) Registration in the EU database (when applicable). 2) Copy of authorisation/ethics approval to conduct clinical trial. 3) Copy of the insurance and liability details.
	Is it a low-intervention clinical trial?	☐	☐	1) Details on the medical products that are being used and risk assessment. 2) Details on the disease/condition /disability of the participants 3) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 4) Details on the incidental findings	1) Registration in the EU database (when applicable). 2) Copy of authorisation/ethics approval to conduct clinical trial. 3) Copy of the insurance and liability details.

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3 HUMAN CELLS / TISSUES		YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve the use of human cells or tissues (other than those covered by *section 1*)**?**		☐	☐	Please provide information in one of the subcategories below.	
If **YES:**	Are they human embryonic or foetal cells or tissues?	☐	☐	1) Origin of human foetal tissues/cells. 2) Details on informed consent procedures. 3) Confirmation that the informed consent has been obtained. 4) If applicable, details on the induced human pluripotent cell lines.	1) Copies of ethics approvals. 2) Informed consent forms and information Sheets. 3) If applicable, registration certificates of the cell lines and project from the hPSCreg.
	Are they available commercially?	☐	☐	1) Details on cell types and provider (company or other).	1) Copies of import licences (if relevant).
	Are they obtained within this project?	☐	☐	1) Details on cell types including the source of the material, the amount to be collected and the procedure for collection. 2) Details on the duration of storage and what will be done with the material at the end of the activity. 3) Confirmation that informed consent has been obtained.	1) Copies of ethics approvals (if relevant). 2) Informed consent forms and information sheets.
	Are they obtained from another project, laboratory or institution?	☐	☐	1) Details on cell types. 2) Country where the material is stored. 3) Details of the legislation under which material is stored.	1) Authorisation by primary owner of cells/tissues (including references to ethics approvals) 2) Copies of import

Is it planned to export personal data (data transfer) from the EU to non-EU countries? *Specify the type of personal data and countries involved*	☐	☐	1) Details of the types of personal data and countries involved. 2) Explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded	1) Confirmation that data transfers will be made in accordance with Chapter V of the General Data Protection Regulation 2016/679
Is it planned to import personal data (data transfer) from non-EU countries into the EU or from a non-EU country to another non-EU country? *Specify the type of personal data and countries involved*	☐	☐	1) Details of the types of personal data and countries involved.	1) Confirmation of compliance with the laws of the country in which the data was collected.
Does your activity involve the processing of personal data related to criminal convictions or offences?	☐	☐	1) Details on the personal data to be processed and the legal basis for the processing; 2) Risk assessment for the data processing operations. 3) Explanation as to how harm will be prevented and the rights of the participants/data subjects will be safeguarded.	1) Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR (if relevant).

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